



Billing Code 4410-09-M

DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
IMPORTER OF CONTROLLED SUBSTANCES
NOTICE OF REGISTRATION
CARACO PHARMACEUTICAL LABORATORIES, LTD.

By Notice dated February 8, 2013, and published in the Federal Register on February 21, 2013, 78 FR 12101, Caraco Pharmaceutical Laboratories, Ltd., 270 Prospect Plains Road, Cranbury, New Jersey 08512, made application to the Drug Enforcement Administration (DEA) to be registered as an importer of Fentanyl (9801), a basic class of controlled substance listed in schedule II.

The company plans to import the listed controlled substance in finished dosage form for clinical trials, and research.

The import of the above listed basic class of controlled substance is granted only for analytical testing and clinical trials. This authorization does not extend to the import of finished FDA approved or non-approved dosage form for commercial distribution in the United States.

No comments or objections have been received. DEA has considered the factors in 21 USC § 823(a) and § 952(a), and determined that the registration of Caraco Pharmaceutical

Laboratories, Ltd., to import the basic class of controlled substance is consistent with the public interest, and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. DEA has investigated Caraco Pharmaceutical Laboratories, Ltd., to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history.

Therefore, pursuant to 21 USC § 952(a) and § 958(a), and in accordance with 21 CFR § 1301.34, the above named company is granted registration as an importer of the basic class of controlled substance listed.

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration

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